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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,920	09/22/2003	Dimitrios Manoussakis	3896-030965 (P-6015)	9903

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EXAMINER

ROY, ANURADHA

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/667,920

**Applicant(s)**

MANOUSSAKIS, DIMITRIOS

**Examiner**

Anuradha Roy

**Art Unit**

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/22/03 & 4/7/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10, 11, 17-19, & 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Columbus (US Patent No. 4,050,451).

Regarding claims 1 & 17, Columbus discloses a specimen collection container comprising: a collection container (assembly in Figure 2) comprising a non-evacuated collection tube (32 & Column 5, lines 36-46) including a cylindrical tubular wall extending between an open top end and an open bottom end (32) defining an interior chamber therebetween, a piercible closure (38) sealing said open top end of said collection tube, and a venting closure (42 & 38) sealing said open bottom end of said collection tube, said venting closure adapted for displacement of air from said interior chamber of said collection tube to an exterior of said collection tube during collection of a liquid sample within said interior chamber of said collection tube.

Furthermore, regarding claim 37, Columbus discloses a method for collecting a biological sample comprising the steps of: a) providing a non-evacuated collection tube (assembly of Figure 2) including a vent (42) adapted for displacement of air from within said collection tube to an exterior environment and a piercible closure (38) providing access to the interior of said collection tube; b) accessing the interior of said collection tube through said piercible closure (11 & 38); and c) transferring a biological sample through said piercible closure into said interior of said collection tube (11, 32, & 38) such that any air present within said interior of said collection tube will vent (42) to the exterior environment through said vent during such transferring step.

Regarding claim 38, Columbus discloses a method, wherein said accessing step comprises establishing fluid communication between a blood vessel of a patient and the interior of said collection tube (11 & 32), such that blood pressure causes transferring of blood from the blood vessel to the interior of the collection tube (Column 5, lines 36-46).

With regards to claims 2, 3, 4, 18, 19, & 39, Columbus discloses a specimen collection container, wherein said vent (42) is adapted for maintaining said interior chamber at ambient pressure prior to collection of a sample within said interior chamber, further comprising a two-way vent, wherein said vent is adapted to seal upon contact with said liquid sample so as to prevent said displacement of air (Column 5, lines 11-20).

Regarding claim 5, 6 & 7, Columbus discloses a specimen collection container, wherein said bottom end (36) of said collection container is open, said specimen collection container further comprising a bottom closure sealing (38) said open bottom end of said collection tube with said vent extending through at least a portion of said bottom closure (42). Furthermore, Columbus discloses a specimen collection container, wherein said top closure (38) is removably attached to said open top end (34) of said collection tube and said bottom closure (38) is removably attached to said bottom end (36) of said collection tube and comprises a hybrid stopper (38) removably attachable to said open bottom end.

Regarding claims 10 & 11, Columbus discloses a specimen collection container, wherein said vent (42) extends through at least a portion of said piercible closure and the piercible closure comprises a hybrid stopper (38) removably attachable to said open top end (34).

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 9, 12-16, 20-36, & 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus in view of Bodner et al. (US Patent No. 6,805,842).

Regarding claims 14, 15, 16, 22, 23, 24, 25, 26, 27, 28, & 40, Columbus discloses a specimen collection container (assembly in Figure 2) comprising a non-evacuated collection tube (32 & Column 5, lines 36-46) including a cylindrical tubular wall (32) extending between an open top end and an open bottom end defining an interior chamber therebetween, a piercible closure (38) sealing said open top end of said collection tube, and a venting closure (42 & 38) sealing said open bottom end of said collection tube, said venting closure adapted for displacement of air from said interior chamber of said collection tube to an exterior of said collection tube during collection of a liquid sample within said interior chamber of said collection tube. Columbus, however, does not disclose the use of an internal container, or expandable bag, positioned within the interior chamber of said collection tube and in sealed engagement with said open top end of said collection tube where the internal container establishes a closed environment for containment of a liquid sample. Furthermore, Columbus does not teach of the expandable bag mated with the top end of said collection tube and the piercible closure. However, Bodner et al. discloses, the use of an internal container, or

expandable bag (160), positioned within the interior chamber of said collection tube and in sealed engagement with said open top end of said collection tube (Column 2, lines 66-67 & Column 3, lines 1-3), said internal container establishing a closed environment for containment of a liquid sample. Bodner also teaches of the expandable bag (160) mated with the top end of said collection tube and the piercible closure (Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include an expandable bag so that it is “substantially reducible to the volume of liquid contained within it and is substantially devoid of air or of the external atmosphere” (Column 3, lines 10-13).

Regarding claims 8, 12, 20, & 35, Columbus discloses specimen collection container with the aforementioned elements and a venting filter (44). However, Columbus fails to directly disclose a hybrid stopper comprised of an elastomeric material. Bodner et al, however, further discloses the use of an elastomeric material for the hybrid stopper (Column 4, lines 27-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an elastomeric material to establish a self-sealing property on the membrane in order to ensure that air does not enter the expandable bag, thereby minimizing evaporation.

Regarding claims 9, 13, 21, & 36, Columbus discloses a specimen collection container, wherein said venting filter comprises a material selected from the group

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consisting of high density polyethylene and high density polypropylene (Column 6, lines 16-19).

Regarding claims 29, 30, & 31, Columbus discloses a specimen collection container, wherein said vent (42) is adapted for maintaining said interior chamber at ambient pressure prior to collection of a sample within said interior chamber, further comprising a two-way vent, wherein said vent is adapted to seal upon contact with said liquid sample so as to prevent said displacement of air (Column 5, lines 11-20).

Regarding claims 32, 33, & 34, Columbus discloses a specimen collection container, wherein said bottom end (36) of said collection container is open, said specimen collection container further comprising a bottom closure sealing (38) said open bottom end of said collection tube with said vent extending through at least a portion of said bottom closure (42). Furthermore, Columbus discloses a specimen collection container, wherein said top closure (38) is removably attached to said open top end (34) of said collection tube and said bottom closure (38) is removably attached to said bottom end (36) of said collection tube and comprises a hybrid stopper (38) removably attachable to said open bottom end.

### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kelly et al. (US Patent No. 6,179,787), Greenspan (US Patent



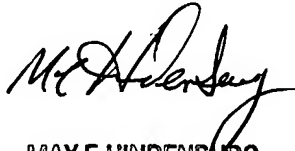
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No. 4,202,769), and Adams et al. (US Patent No. 5,419,835) disclose a two-ended collection assembly with piercible closures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~

  
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